



## Stability Data Summary

Generated Date: 13-SEP-2013 09:24:16

Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: 0A0A7

Storage Condition: 25C/60% RH

Generic Name/Strength: S Solu-Medrol 500 MG

Stability Study Start Date: 30-MAR-2009

Manufacturing Site: KALAMAZOO

Manufacture Date: 05-JAN-2009

Batch/Lot Number: 0A0A7

Batch Size: 36451 BOTTLES

Expiration Date: 31-DEC-2012

Product/Package Code: VIAL - 500 MG

Packaging Description: 500mg/20 ml vial

Purpose of Study: Stability Lot



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Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: 0A0A7

Storage Condition: 25C/60% RH

Components	Procedure	Units	TIME ZERO	12 MONTHS	24 MONTHS	36 MONTHS
APPEARANCE	VISUAL		MEETS TEST	MEETS TEST	MEETS TEST	MEETS TEST
FREE METHYLPRED %	TA5425	%	1.1	1.1	1.6	1.4
FREE METHYLPRED RECONSTITUTE %	TA0405	%	4.1	NR	NR	NR
LOSS ON DRYING %	GP0143	%	0.2	0.2	0.4	0.7
METHYLPREDNISOL MG/8 ML	TA5425	mg/8 mL	517	509	501	501
PARTICULATE MAT	GP0333		MEETS TEST	MEETS TEST	MEETS TEST	MEETS TEST
PARTICULATE MAT >=10MICRONS PART/CONTAIN	GP0333	Particles/Container	36	24	482	70
PARTICULATE MAT >=25MICRONS PART/CONTAIN	GP0333	Particles/Container	1	2	8	3
PH	PH		7.6	7.5	7.5	7.48
PH RECONSTITUTE	TA0405		NR	NR	NR	NR
PH RECONSTITUTE	TA0405		7.4	NR	NR	NR
SOLUBILITY SEC	DM0035	s	49	29	27	28
STERILITY	TA8230		NR	NR	NR	NR

Legend:

NR = Not Required

---- = Data not available



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Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: 0A0A7

Storage Condition: 25C/60% RH

Components	Procedure	Units	EXPIRY
APPEARANCE	VISUAL		MEETS TEST
FREE METHYLPRED %	TA5425	%	2.0
FREE METHYLPRED RECONSTITUTE %	TA0405	%	3.9
LOSS ON DRYING %	GP0143	%	0.5
METHYLPREDNISOL MG/8 ML	TA5425	mg/8 mL	509
PARTICULATE MAT	GP0333		MEETS TEST
PARTICULATE MAT >=10MICRONS PART/CONTAIN	GP0333	Particles/Container	203
PARTICULATE MAT >=25MICRONS PART/CONTAIN	GP0333	Particles/Container	15
PH	PH		7.5
PH RECONSTITUTE	TA0405		7.3
PH RECONSTITUTE	TA0405		NR
SOLUBILITY SEC	DM0035	s	19
STERILITY	TA8230		MEETS TEST

Legend:

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Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: 0A0A7

Storage Condition: 25C/60% RH

Components	Procedure	Units	TIME ZERO	12 MONTHS	24 MONTHS	36 MONTHS
METHYLPRED EQUI RECONSTITUTE MG/8 ML	TA0405	mg/8 mL	507	NR	NR	NR
STERILITY RESUL	TA8280		MEETS TEST	NR	NR	NR

Legend:

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Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: 0A0A7

Storage Condition: 25C/60% RH

Components	Procedure	Units	EXPIRY
METHYLPRED EQUI RECONSTITUTE MG/8 ML	TA0405	mg/8 mL	509
STERILITY RESUL	TA8280		NR

Legend:

NR = Not Required

---- = Data not available



## Stability Data Summary

Generated Date: 20-SEP-2012 08:02:32

Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: 0AFYA

Storage Condition: 25C/60% RH

Generic Name/Strength: S Solu-Medrol 500 MG

Stability Study Start Date: 03-JAN-2008

Manufacturing Site: KALAMAZOO

Manufacture Date: 02-OCT-2007

Batch/Lot Number: 0AFYA

Batch Size: 36451 BOTTLES

Expiration Date: 31-OCT-2011

Product/Package Code: VIAL - 500 MG

Packaging Description: 500 mg/20 ml flint glass vial

Purpose of Study: Stability Lot



## Stability Data Summary

Generated Date: 20-SEP-2012 08:02:32

Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: 0AFYA

Storage Condition: 25C/60% RH

Components	Procedure	Units	TIME ZERO	12 MONTHS	24 MONTHS	36 MONTHS
SOLUBILITY SEC	DM0035	s	19	20	28	25
LOSS ON DRYING %	GP0143	%	0.1	0.2	0.2	0.3
PARTICULATE MAT	GP0333		MEETS TEST	MEETS TEST	MEETS TEST	MEETS TEST
PARTICULATE MAT ≥10MICRONS PART/CONTAIN	GP0333	Particles/Container	304	15	8	110
PARTICULATE MAT ≥25MICRONS PART/CONTAIN	GP0333	Particles/Container	8	2	0	2
PH	PH		7.7	7.6	7.6	7.5
FREE METHYLPRED RECONSTITUTE %	TA0405	%	3.5	NR	NR	NR
PH RECONSTITUTE	TA0405		7.4	NR	NR	NR
METHYLPRED EQUI RECONSTITUTE MG/8 ML	TA0405	mg/8 mL	518	NR	NR	NR
FREE METHYLPRED %	TA5425	%	1.1	1.4	1.3	1.5
METHYLPREDNISOL MG/8 ML	TA5425	mg/8 mL	524	505	505	498
STERILITY RESUL	TA8280		MEETS TEST	NR	NR	NR
APPEARANCE	VISUAL		MEETS TEST	MEETS TEST	MEETS TEST	MEETS TEST

Legend:

NR = Not Required

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## Stability Data Summary

Generated Date: 20-SEP-2012 08:02:32

Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: 0AFYA

Storage Condition: 25C/60% RH

Components	Procedure	Units	46 MONTHS
SOLUBILITY SEC	DM0035	s	29
LOSS ON DRYING %	GP0143	%	0.4
PARTICULATE MAT	GP0333		MEETS TEST
PARTICULATE MAT >=10MICRONS PART/CONTAIN	GP0333	Particles/Container	90
PARTICULATE MAT >=25MICRONS PART/CONTAIN	GP0333	Particles/Container	4
PH	PH		7.5
FREE METHYLPRED RECONSTITUTE %	TA0405	%	3.0
PH RECONSTITUTE	TA0405		7.5
METHYLPRED EQUI RECONSTITUTE MG/8 ML	TA0405	mg/8 mL	498
FREE METHYLPRED %	TA5425	%	1.6
METHYLPREDNISOL MG/8 ML	TA5425	mg/8 mL	499
STERILITY RESUL	TA8280		MEETS TEST
APPEARANCE	VISUAL		MEETS TEST

Legend:

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## Stability Data Summary

Generated Date: 20-SEP-2012 08:02:32

Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: 0AFYA

Storage Condition: 30C/65% RH

Generic Name/Strength: S Solu-Medrol 500 MG

Stability Study Start Date: 03-JAN-2008

Manufacturing Site: KALAMAZOO

Manufacture Date: 02-OCT-2007

Batch/Lot Number: 0AFYA

Batch Size: 36451 BOTTLES

Expiration Date: 31-OCT-2011

Product/Package Code: VIAL - 500 MG

Packaging Description: 500 mg/20 ml flint glass vial

Purpose of Study: Stability Lot



## Stability Data Summary

Generated Date: 23-SEP-2014 15:31:53

Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: A1AMK

Storage Condition: 25C/60% RH

Generic Name/Strength: S Solu-Medrol 500 MG

Stability Study Start Date: 13-MAY-2010

Manufacturing Site: KALAMAZOO

Manufacture Date: 29-JAN-2010

Batch/Lot Number: A1AMK

Batch Size: 36266 BOTTLES

Product/Package Code: VIAL - 500 MG

Packaging Description: 500 mg/20 ml vial

Purpose of Study: Stability Lot



## Stability Data Summary

Generated Date: 23-SEP-2014 15:31:53

Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: A1AMK

Storage Condition: 25C/60% RH

Components	Procedure	Units	TIME ZERO	12 MONTHS	24 MONTHS	36 MONTHS
APPEARANCE	VISUAL		MEETS TEST	MEETS TEST	MEETS TEST	MEETS TEST
FREE METHYLPRED %	TA5425	%	1.3	1.6	1.1	1.8
FREE METHYLPRED RECONSTITUTE %	TA0405	%	3.5	NR	NR	NR
LOSS ON DRYING %	GP0143	%	LT 0.1	0.1	0.4	0.3
METHYLPREDNISOL MG/8 ML	TA5425	mg/8 mL	512	504	501	514
PARTICULATE MAT	GP0333		MEETS TEST	MEETS TEST	MEETS TEST	MEETS TEST
PARTICULATE MAT >=10MICRONS PART/CONTAIN	GP0333	Particles/Container	27	161	254	383
PARTICULATE MAT >=25MICRONS PART/CONTAIN	GP0333	Particles/Container	0	3	6	4
PH	PH		7.5	7.6	7.6	7.5
PH RECONSTITUTE	TA0405		NR	NR	NR	NR
PH RECONSTITUTE	TA0405		7.4	NR	NR	NR
SOLUBILITY SEC	DM0035	s	10	24	24	19
METHYLPRED EQUI RECONSTITUTE MG/8 ML	TA0405	mg/8 mL	504	NR	NR	NR

Legend:

NR = Not Required

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## Stability Data Summary

Generated Date: 23-SEP-2014 15:31:53

Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: A1AMK

Storage Condition: 25C/60% RH

Components	Procedure	Units	48 MONTHS
APPEARANCE	VISUAL		MEETS TEST
FREE METHYLPRED %	TA5425	%	1.9
FREE METHYLPRED RECONSTITUTE %	TA0405	%	3.5
LOSS ON DRYING %	GP0143	%	0.7
METHYLPREDNISOL MG/8 ML	TA5425	mg/8 mL	500
PARTICULATE MAT	GP0333		MEETS TEST
PARTICULATE MAT >=10MICRONS PART/CONTAIN	GP0333	Particles/Container	114
PARTICULATE MAT >=25MICRONS PART/CONTAIN	GP0333	Particles/Container	2
PH	PH		7.5
PH RECONSTITUTE	TA0405		7.3
PH RECONSTITUTE	TA0405		NR
SOLUBILITY SEC	DM0035	s	34
METHYLPRED EQUI RECONSTITUTE MG/8 ML	TA0405	mg/8 mL	502

Legend:

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## Stability Data Summary

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Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: A1AMK

Storage Condition: 25C/60% RH

Components	Procedure	Units	TIME ZERO	12 MONTHS	24 MONTHS	36 MONTHS
STERILITY RESUL	TA8280		MEETS TEST	NR	NR	NR

Legend:

NR = Not Required

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## Stability Data Summary

Generated Date: 23-SEP-2014 15:31:53

Product Name/Strength: SOLU-MEDROL 500 MG, S, SOLU-MEDROL - 481096

Stability Study Name: A1AMK

Storage Condition: 25C/60% RH

Components	Procedure	Units	48 MONTHS
STERILITY RESUL	TA8280		MEETS TEST

Legend:

NR = Not Required

---- = Data not available